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THE ROYAL FREE HAMPSTEAD
Royal Free Hospital
NHS TRUST

ETHICAL PRACTICES SUB-COMMITTEE
RFH

7th January 1997

RECEIVED
01 JAN 1997
PROF
GASTROENTEROLOGY

Prof J. Walker-Smith,
Department of Paediatric Gastroenterology,
RFH.

Dear Prof Walker-Smith

Re: 172-96 - A new paediatric syndrome: Enteritis and disintegrative disorder following measles/rubella vaccination

I refer to your recent application to the Ethics Committee regarding the above project and I am pleased to inform you that the project was approved at the meeting on 18th December 1996. This approval is for two years from the date of this letter. Extension of this period will be dependant on the submission of a brief synopsis of the progress of the project together with an estimation of the time required for its ultimate completion.

As you may be aware this application was discussed at length at two committee meetings and the approval is conditional on the following:

1) Only patients enrolled after the date of the December meeting will be considered to be in the trial

2) The Shilling test to be removed from the protocol

3) The consent form to be modified so that the possible complications of lumbar puncture are explained

The Ethics Committee will require an annual report on the progress of the study and a copy of the completed study together with any consequent publication. In addition the Committee must be informed, by the completion of the relevant form, of any untoward or adverse events which occur during the course of the study. The person who provided independent review of the original protocol should also be sent information regarding adverse events.

The ethics committee must also be informed of, and approve, any proposed amendment to your initial application which has a bearing on the treatment or investigation of patients or volunteers.

A copy of the patient consent form and information sheet must be lodged in the clinical notes.

Furthermore, whilst I am sure that every effort is already made to preserve the confidentiality of any patient information used in this study, could you please ensure that the team of investigators are aware that everyone who has access to patient information appreciates the importance of maintaining confidentiality particularly in respect of the use of computers and the statutory regulations laid down in the Data Protection Act 1984.

Yours sincerely,

M.S. Pegg

Dr Michael S. Pegg LLM, MD, BS, FRCA
Chairman,
Royal Free Hospital & Medical School Ethics Committee